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A Bittersweet Deal for Consumers: The Unnatural Application of Preemption to High Fructose Corn Syrup Labeling Claims

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A BITTERSWEET DEAL FOR CONSUMERS: THE UNNATURAL APPLICATION OF PREEMPTION TO HIGH FRUCTOSE CORN SYRUP LABELING CLAIMS

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I. INTRODUCTION

The recent rise of consumer consciousness regarding the health qualities of foods and beverages has become something akin to common knowledge. Reflecting this rise, studies reveal that labels regarding the health qualities of a food are more likely to increase sales.[1] And among the health labels consumers prefer, labels describing the product as natural top the list. One website reports that according to a recent study, 31.3-percent of respondents thought that "100% natural" was the best description to read on a label, compared with only 14.2-percent who thought that "100% organic" was the best description.[2] "All natural ingredients" was the second most preferred description; it was preferred by 25.4-percent of respondents.[3] Because it is such a powerful phrase in labeling, how the term "natural" should be used is a hotly contested issue.

Equally pervasive in consumer food and beverage products is the use of high fructose corn syrup (HFCS), a sweetener found in a variety of food and beverage products including yogurt, sauces and condiments, energy bars, and frozen beverage concentrates.[4] Developed in Japan in 1971, HFCS is cheap to produce, and is six times sweeter than cane sugar.[5] At a time when cane sugar prices were artificially high due to trade issues, HFCS became the sweetener of choice for food manufacturers, and its use has remained widespread.[6]

In recent years, several lawsuits have been filed contesting the use of the phrase "natural" on products that contain HFCS. The common factual basis for the claims is that HFCS is allegedly not

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1. Claudia Andre, *What's In That Guacamole? How Bates And The Power Of Preemption Will Affect Litigation Against The Food Industry*, 15 GEO. MASON L. REV. 227, 254 (2007).

2. John Laumer, *US Consumers Prefer "100% Natural" Food Label*, TREEHUGGER (Jul. 3, 2009), http://www.treehugger.com/files/2009/07/us-customers-prefer-natural-label-100-organic.php.

3. *Id.*

4. Jennifer Nelson, *High Fructose Corn Syrup: What Are The Concerns?*, MAYO CLINIC (Oct. 23, 2010), http://www.mayoclinic.com/health/high-fructose-corn-syrup/AN01588; *High Fructose Corn Syrup In Foods And Beverages*, SWEETSURPRISE, http://sweetsurprise.com/learning-center/why-is-hfcs-used (last visited Dec. 27, 2010)

5. GREG CRITSER, FAT LAND: HOW AMERICANS BECAME THE FATTEST PEOPLE IN THE WORLD 10 (2003).

6. *Id.* at 11.

natural, and that by placing the term "natural" on products containing HFCS, defendant-manufacturers are misleading consumers.[7]

The legal theories pursued by plaintiffs upon this factual basis include violations of state-law consumer fraud and unfair competition statutes, unjust enrichment, and breach of warranty claims.[8] The most common legal defenses used by defendants seeking summary judgment are preemption and primary jurisdiction.[9] This paper focuses exclusively on the former.

According to the author's count, there are presently nine cases involving the use of "natural" on products containing HFCS that are being litigated or have been recently decided.[10] The products involved include granola bars, pasta sauce, iced tea, and juice drinks.[11] The current hotbeds of this litigation are New Jersey and California. All of the decisions in cases on this issue were given in 2009 or 2010, save one, which was given in June 2008.[12] This suggests that this field of litigation is in its infancy, and can be expected to grow.

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7. Holk v. Snapple Beverage Corp., 575 F.3d 329, 332 (3d Cir. 2009).

8. *Id.*; Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1029 (N.D. Cal. 2009).

9. For an explanation of preemption doctrine, *see infra*, section 2. Though this paper does not focus on primary jurisdiction, note that several courts have recently stayed proceedings in "natural" cases based on primary jurisdiction grounds, in order to refer the definition of "natural" to the FDA. However, all of the stays were temporary, and most have been lifted due to the FDA's express refusal to consider the issue. *See, e.g.*, Holk v. Snapple Beverage Corp., No. 07-3018, 2010 WL 4065390 (D.N.J. Oct. 15, 2010) (order granting motion to reopen the action); Coyle v. Hornell Brewing Co., No. 08-2797 (D.N.J. Sept. 23, 2010) (order dissolving temporary stay).

10. Those cases are: Holk v. Snapple Beverage Corp., 575 F.3d 329 (3d Cir. 2009); Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028 (N.D. Cal. 2009); Covington v. Arizona Beverage Co., No. 1:08 21894 (S.D. Fla.) (*see In re* Arizona Beverage Co. Products Marketing and Sales Practice Litigation, 609 F. Supp. 2d 1369 (J.P.M.L. 2009)); Coyle v. Hornell Brewing Co., No. 08-2797, 2009 WL 1652399 (D.N.J. June 9, 2009); Hitt v. Arizona Beverage Co., No. 08cv809, 2009 WL 449190 (S.D. Cal. Feb. 4, 2009); Wright v. General Mills, Inc., No. 08cv1532, 2009 WL 3247148 (S.D. Cal. Sept. 30, 2009); Von Koenig v. Snapple Beverage Corp., 713 F. Supp. 2d 1066 (E.D. Cal. 2010); Weiner v. Snapple Beverage Corp., No. 07 Civ. 8742, 2010 WL 3119452 (S.D.N.Y. Aug. 5, 2010); Ries v. Hornell Brewing Co., No. 10-1139-JF 2010 WL 2943860 (N.D. Cal. July 23, 2010). Additionally, in 2007, both Cadbury Schweppes and Kraft were threatened with lawsuits regarding "natural" claims on 7Up and Capri Sun drinks, but changed the labels before the matter was resolved legally. Laura Crowley, *HFCS is Natural, Says FDA in a Letter*, FOOD NAVIGATOR-USA (July 8, 2008), http://www.foodnavigator-usa.com/Financial-Industry/HFCS-is-natural-says-FDA-in-a-letter.

11. *Id.*

12. *Id.*

It is the position of the author that the claims being pursued by plaintiffs in cases on this issue are not preempted by federal law, but that clarification of the Food and Drug Administration's (FDA) labeling policy and the general curtailment of FDA labeling authority would best serve consumers. This paper will provide a brief background on the FDA's authority to regulate food products, followed by a brief history of litigation on point. It will then provide a brief overview of current preemption doctrine, and seek to apply that doctrine to the common factual issues regarding the use of "natural" on products containing HFCS.[13] Finally, it will conclude by encouraging greater clarity from the FDA, and a retreat from the agency's control of labeling in general.

A. FDA Authority to Regulate Food Products

Federal governmental regulation of the food industry began in earnest with the passing of the Food and Drug Act of 1906, which permitted regulation of certain labels.[14] This authority, initially given to the Bureau of Chemistry, was expanded in 1912.[15] Then, in 1938, Congress passed the Federal Food Drug and Cosmetic Act (FDCA), which further expanded regulatory authority, and which formed the basis for the modern incarnation of the FDCA.[16] Subsequent legislation in 1946 and 1970 revised the FDCA, and in doing so signaled a trend toward consumer protection concerns in labeling.[17] This trend culminated in the passage of the Nutritional Labeling and Education Act of 1990 (NLEA), the contents of which form the basis for the legal issue discussed in this comment.

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13. Though the immediate focus of this paper is the use of "natural" in relation to HFCS, its implied preemption analysis reaches the broader issue of the FDA policy on the use of "natural," and thus may provide useful insight for a broad range of specific issues under the "natural" umbrella.

14. MARION NESTLE, FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH 233 (2002). This act is also known as the "Wiley Act." Holk v. Snapple Beverage Corp., 575 F.3d 329, 331 (3d Cir. 2009).

15. *Id.*

16. Claudia Andre, *What's In That Guacamole? How Bates And The Power Of Preemption Will Affect Litigation Against The Food Industry*, 15 GEO. MASON L. REV. 227, 230 (2007).

17. *Id.* at 231.

B. Survey of Cases

In 2007, Stacy Holk filed a class action claim against Snapple Beverage Corporation regarding the use of "natural" on its juice drinks.[18] This claim was dismissed by the district court on the ground of implied field preemption.[19] That ruling was reversed by the Third Circuit.[20] In the time between the district court *Holk* ruling and the appellate court *Holk* ruling, five additional district court rulings involving the use of "natural" on products containing HFCS were issued. Of these, two were substantive rulings on motions to dismiss (which were denied in both cases),[21] and three were procedural.[22] There have been numerous rulings since then, but aside from the district court *Holk* case, no court that has considered the issue has found the plaintiffs' claims to be preempted, expressly or impliedly.[23]

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18. Holk v. Snapple Beverage Corp., 574 F. Supp. 2d 447 (D.N.J. 2008). This claim was originally filed in New Jersey state court, but was removed to federal court. *See* Holk v. Snapple Beverage Corp., No. 07cv03018, 2007 WL 4677862 (D.N.J. June 29, 2007).

19. Holk v. Snapple Beverage Corp., 574 F. Supp. 2d 447 (D.N.J. 2008).

20. Holk v. Snapple Beverage Corp., 575 F.3d 329 (3d Cir. 2009).

21. In one of these cases, *Hitt v. Arizona Beverage Co.*, the plaintiff subsequently decided that she did not want to pursue the case as a class representative, and filed a motion to amend. In an order dated Nov. 24, 2009, the court gave her 20 days to file a motion for voluntary dismissal or an affidavit stating that she would pursue the action as the named plaintiff and class representative. Her final decision is unknown at this time. Hitt v. Arizona Beverage Co., No. 08cv809, 2009 WL 4261192 (S.D. Cal. Nov. 24, 2009).

22. In *Wright v. General Mills, Inc.*, the court denied the defendant's motion to dismiss on the ground of preemption, but granted it without prejudice for plaintiff's failure to state a claim. Wright v. General Mills, Inc., No. 08cv1532, 2009 WL 3247148 (S.D. Cal. Sept. 30, 2009). In *Hitt v. Arizona Beverage Co.*, the court denied the defendant's motion to dismiss. Hitt v. Arizona Beverage Co., No. 08cv809, 2009 WL 449190 (S.D. Cal. Feb. 4, 2009). In *Coyle v. Hornell Brewing Co.*, the court affirmed a Magistrate Judge's order denying the defendant's application for a stay of discovery pending the resolution of the *Holk* appellate case. Coyle v. Hornell Brewing Co., No. 08-2797, 2009 WL 1652399 (D.N.J. June 9, 2009). In a third ruling, a judicial panel on multidistrict litigation denied a motion to centralize three separate actions against Arizona Beverage Co. (one of which was *Coyle*). *In re* Arizona Beverage Co. Products Marketing And Sales Practices Litigation, 609 F. Supp. 2d 1369 (J.P.M.L. 2009).

23. *See supra* note 9.

II. RULES OF PREEMPTION

Preemption occurs when federal law bars the enforcement of state law requirements. The legal basis for preemption rests in the Supremacy Clause of Article VI of the Constitution, which provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[24] State law may be preempted expressly or impliedly.[25]

Express preemption occurs when Congress designates the specific types of state law requirements that are preempted.[26] A common ancillary feature of express preemption provisions is a savings clause, which specifies what types of state-law requirements are *not* preempted by the federal law in question.

Implied preemption may occur in two ways: a.) Implied field preemption; and b.) Implied conflict preemption. Implied field preemption occurs when state law regulates "in a field that Congress intended the Federal Government to occupy exclusively."[27] There are two ways to infer Congressional intent to preempt the field. One is the presence of a "scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it."[28] The other is where an Act of Congress touches "a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."[29]

Implied conflict preemption can also occur in two situations. It can occur when it is "impossible for a private party to comply with both state and federal requirements."[30] Or it can occur when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[31] And neither the absence of express preemption nor the presence of a savings clause precludes implied conflict preemption. As the Supreme Court in *Geier v. American Honda* pointed out, "the saving clause (like the ex-

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24. U.S. CONST. art. VI, cl. 2.
25. Holk v. Snapple Beverage Corp., 575 F.3d 329, 334 (3d Cir. 2009).
26. *See* 21 U.S.C. § 343-1 (2006) (example of an express preemption clause).
27. English v. General Electric Co., 496 U.S. 72, 79 (1990).
28. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).
29. *Id.*
30. English v. General Electric Co., 496 U.S. 72, 78-79 (1990).
31. Holk v. Snapple Beverage Corp., 575 F.3d 329, 339 (3d Cir. 2009) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

press pre-emption provision) does *not* bar the ordinary working of conflict pre-emption principles."[32]

Further, federal statutory law is not the only federal law with preemptive effect. Federal agency regulations may preempt state law as well.[33] As the Third Circuit noted, "[w]here Congress has delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes."[34]

A. Presumption Against Preemption

The Supreme Court has said that "[c]onsideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by... Federal Act unless that [is] the clear and manifest purpose of Congress.' "[35] This assumption operates as a presumption against preemption.[36] The idea that regulation of food labeling falls within the province of state regulation dates back to at least 1894, when the Supreme Court, in *Plumley v. Commonwealth of Massachusetts*, noted that "[i]f there be any subject over which it would seem the states ought to have plenary control... it is the protection of the people against fraud and deception in the sale of food products."[37]

Nor did the advent of the FDCA take regulation of food labeling out of the province of state authority. The Supreme Court reaffirmed the principle stated in *Plumley* in a 1963 case.[38] And in 2009, the Court specifically rejected an argument that the presumption against preemption should not be applied to drug labeling - which is regulated under the FDCA along with food labeling - merely because the federal government has regulated drug labeling for more than a century.[39] Thus, even the century-long tradition of federal regulation of food labeling under the FDCA cannot take the matter out of the states' police power.

The practical effect of the presumption is that if a court is faced with two equally plausible interpretations of a text, it has a "duty to

32. Geier v. American Honda Motor Co., 529 U.S. 861, 869 (2000).
33. Wyeth v. Levine, 129 S. Ct. 1187, 1200 (2009).
34. Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 243 (3d Cir. 2008).
35. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).
36. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).
37. 155 U.S. 461, 472 (1894).
38. Florida Lime and Avocado Growers, Inc. v. Paul, 373 U.S. 132, 144 (1963).
39. Wyeth v. Levine, 129 S.Ct. 1187, 1195 n.3 (2009).

accept the reading that disfavors pre-emption."[40] Further, the presumption applies not only to the question of whether preemption exists at all, but also to the question of the scope of preemption.[41]

III. EXPRESS PREEMPTION

Because the purpose of Congress is the ultimate touchstone in every preemption case, preemption analysis should begin with express preemption, where Congressional intent is most clearly communicated.[42] Because the state law causes of action examined in this article involve labeling, the express preemption provision governing any issues that might arise in connection with the use of the term "natural" on food and beverage labels is 21 U.S.C. § 343-1(a). This statute, labeled "National Uniform Nutrition Labeling," is the only express preemption statute in the NLEA, and limits the requirements that states can establish as to certain products regulated under 21 U.S.C. § 341 and 21 U.S.C. § 343.[43] As to these products, states cannot establish any requirements that are "not identical to" the requirements already imposed by 21 U.S.C. § 341 and 21 U.S.C. § 343.[44] The exact text of the statute reads as follows:

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce–
>
> (1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a

40. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

41. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

42. Altria v. Good, 129 S. Ct. 538, 543 (2008).

43. 21 U.S.C. § 343-1(a) (2006).

44. 21 U.S.C. § 343-1(a)(1)-(5) (2006). The FDA has noted that "'[n]ot identical to' does not refer to the specific words in the requirement, but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or (ii) differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act." 21 C.F.R. § 100.1(c)(4) (2010). Further, the definitional breadth of the phrase "of the type required" has not been explicitly defined by courts. While the phrase seems to encompass requirements of a similar *category*, and not just of an identical *effect or wording* (*cf.* 21 U.S.C. § 360k(a) (2006), which seems to suggest a narrower definitional breadth), an authoritative statement of its breadth is impossible at this point.

> standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,
>
> (2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,
>
> (3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,
>
> (4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or
>
> (5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Courts and litigants have tended to give little attention to express preemption in "natural" cases. The defendant in *Holk v. Snapple Beverage Corp.* did not even raise the issue of express preemption in the district court.[45] Nor did the defendant in *Wright v. General Mills, Inc.*[46] Perhaps misunderstanding the law, the defendant in *Hitt v. Arizona Beverage Co.* raised an express preemption defense, but failed to cite a specific express preemption provision that would apply to the plaintiff's claim.[47] The district court briefs in *Lockwood v. Conagra Foods, Inc.* are unavailable, making it impossible to ascertain how detailed the defendant's arguments on express preemption were, but the court's opinion gave the topic little attention.[48] And an article in the *Journal of Food Law and Policy* focusing on the dis-

45. 575 F.3d 329, 335 (3d Cir. 2009).

46. No. 08cv1532, 2009 WL 3247148 (S.D. Cal. Sept. 30, 2009)

47. No. 08cv809, 2009 WL449190 (S.D. Cal. Feb. 4, 2009).

48. Regarding the defendant's 21 U.S.C. § 343(k) preemption claim, the court stated, "[p]laintiffs do not allege that defendant's pasta sauce contains artificial flavoring, coloring, or a chemical preservative," and thus finding § 343(k) inapplicable. Regarding the defendant's 21 U.S.C. § 343(c) claim, the court stated, "[p]laintiffs are not alleging that the pasta sauce is an imitation of some other food," and thus found § 343(c) inapplicable.

trict court *Holk* and *Lockwood* decisions devoted only one paragraph to the express preemption issue.[49]

The above highlighted tendency, which is manifest on all sides of this issue (court, plaintiff, and defendant), might suggest that express preemption is not a persuasive defense as to the use of "natural" in relation to HFCS. Such a suggestion is premature, however, and does not sufficiently account for the complex issues surrounding HFCS and 21 U.S.C. § 343-1.

A. HFCS an Artificial Flavoring?

Snapple's appellate brief in *Holk* raises an express preemption argument that future litigants should not ignore. Central to Snapple's argument is 21 U.S.C. § 343-1(a)(3), which preempts state law requirements for the labeling of food[50] that are of the type required by § 343(k), but that are not identical to the requirements of § 343(k). Section 343(k) applies to "*artificial flavoring*, artificial coloring, or chemical preservatives," and states that foods bearing or containing such components are misbranded unless they bear labeling stating that fact.[51] In its brief, Snapple claimed that the plaintiff's argument that HFCS was not "natural" was "just another way of

49. Adam Schlosser, *A Healthy Diet of Preemption: The Power of the FDA and the Battle Over Restricting High Fructose Corn Syrup From Food and Beverages Labeled 'Natural,'* 5 J. FOOD L. & POL'Y 145 (2009). Schlosser's treatment of express preemption is not only inadequate as to depth, but he also focuses on the wrong analytical aspect of the express preemption arguments being made in HFCS cases. Schlosser suggests that because the claims being raised involve the use of the term "natural," and because the express preemption provision of the NLEA does not mention any FDA regulation on the term "natural," the claims are not expressly preempted. But the use of "natural" only encompasses half of the pertinent subject matter in these suits. The other half is HFCS, which, as the present comment shows, requires a more thoroughgoing analysis in light of 21 U.S.C. § 343-1.

50. The FDA definition of "food" extends to drinks as well. 21 U.S.C. § 321(f)(1) (2006).

51. 21 U.S.C. § 343(k) (2006) (emphasis added). Specifically, the statute states that a food shall be deemed to be misbranded "if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil." *Id.*

saying it is 'artificial.' "[52] Snapple also claimed that HFCS is a "flavoring" within the meaning of 21 C.F.R. § 101.22, which defines flavoring as "any substance, the function of which is to impart flavor."[53]

The conclusion Snapple was trying to reach is obvious: if a plaintiff is essentially arguing that HFCS is "artificial," and if HFCS is a "flavoring," then the plaintiff's claim would seem to be expressly preempted because it seeks the imposition of a state-law requirement of the type required by 21 U.S.C. § 343(k) (i.e. a requirement about artificial flavoring) that is not identical to § 343(k). Snapple's position at least highlights the subtlety of the point at issue, but is its position correct? Leaving aside for now the issue of whether arguing something is not "natural" is just another of way of arguing it is "artificial," Snapple's argument that HFCS is a "flavoring" raises a potentially valid point.

1. Is HFCS a "Flavoring"?

The FDA *appears* to consider HFCS a "nutritive sweetener," which may be distinct from a "flavoring." An examination of the FDA's specific definition of HFCS, found at 21 C.F.R. § 184.1866, supports this interpretation. There, HFCS is defined as a "sweet, nutritive saccharide mixture" which must "conform to the identity and specifications" listed for HFCS in the *Food Chemicals Codex*, 4th Ed.[54] *The Food Chemicals Codex*, in turn, states that the functional use of HFCS in foods is as a "nutritive sweetener." By adopting the *Food Chemicals Codex* identity of HFCS, the FDA appears to consider HFCS a "nutritive sweetener."[55] On the surface, the distinction between "flavoring" and "nutritive sweetener" may appear to be one without a difference, but FDA regulations contain many otherwise common phrases that bear a technical definition within the regulations that is different from their vernacular definition. Such is the case with the terms "flavoring" and "nutritive sweetener."

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52. Brief for Defendant/Appelle Snapple Beverage Corp. at 19, Holk v. Snapple Beverage Corp., 575 F.3d 329 (3d Cir. 2009) (No. 07-3018); Snapple appeals to 21 C.F.R.
§ 101.22 (2010), which distinguishes "natural flavors" from "artificial flavors," for support for this argument.

53. 21 C.F.R. § 101.22(a)(1) (2010).

54. 21 C.F.R. § 184.1866(a)-(b) (2009).

55. The FDA website also appears to consider HFCS a sweetener, in a chart that explains the different functional effects for which ingredients can be added to foods. *Food Ingredients & Colors*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/food/foodingredientspackaging/ucm094211.htm (last updated April 2010).

The technical distinction between these terms is raised in 21 C.F.R. § 170.3(o), where the FDA lists terms that "describe the physical or technical functional effects for which direct human food ingredients may be added to foods."[56] Section 170.3(o)(12) defines "flavoring agents," while § 170.3(o)(21) defines "nutritive sweeteners." These terms are treated as entirely separate technical terms.[57]

But while the terms are treated as entirely separate technical terms, the two categories are not mutually exclusive, and the precise effect for which HFCS is added to a food depends in large part on the manufacturer's intention.[58] According to an FDA representative, "[t]he properties of HFCS would be compatible with use both as a nutritive sweetener and as a flavoring, though use as a sweetener is most common. It is the manufacturer who determines why a substance is added to food."[59]

The fact that an ingredient may serve two simultaneous functional effects, combined with the fact that the intended function is typically determined by the manufacturer, suggests that HFCS could be considered a "flavoring." However, in most cases the ingredient labeling requirements established in 21 § C.F.R. 101.4 and § 101.22 do not require an indication of an ingredient's intended use on a label. The independent and potentially subjective nature of the determination makes a universal declaration of HFCS's functional ef-

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56. 21 C.F.R. § 170.3(o) (2009).

57. The FDA is not the only organization to refer to HFCS as a sweetener. The Corn Refiners Association itself calls HFCS a "corn sweetener." *CRA Petitions FDA for use of "Corn Sugar,"* SWEETSURPRISE.COM (Sept. 14, 2010), http://www.sweetsurprise.com/news-and-press/press-releases/corn-sugar-fda-petition. The website sweetsurprise.com, an advocacy site for HFCS, also calls HFCS a sweetener on its page defining HFCS. *What is HFCS? Learn About Sugar*, SWEETSURPRISE.COM, http://sweetsurprise.com/learning-center/what-is-hfcs (last visited Dec. 27, 2010). Further, in a petition for writ of certiorari to the Supreme Court (on an issue unrelated to labeling), the primary U.S. manufacturers of HFCS referred to HFCS as "the primary sweetener in many baked goods and soft drinks. Petition for Writ of Certiorari, A.E. Staley Mfg. Co. v. Dellwood Farms, Inc., 123 S.Ct. 1254 (2002) (No. 02-736), 2002 WL 32133638, at *5. Finally, Snapple itself stated that HFCS was a sweetener in one of its pleadings in the district court *Holk* case. Reply Memorandum of Law in Further Support of Defendant's Motion to Dismiss Plaintiff's First Amended Class Action Complaint at 33, Holk v. Snapple Beverage Corp., No. 3:07-cv-03018, 2007 WL 4677863 (D.N.J. Nov. 19, 2007).

58. Email from Jeremiah Fasano, Consumer Safety Officer, Food & Drug Admin., to Josh Ashley, J.D. Candidate 2011, Univ. of Arkansas Sch. of Law (Mar. 17, 2010, 08:06:53 CST) (on file with author).

59. *Id.* Note that even though HFCS may in particular be both a flavoring and a sweetener, the FDA has also stated that "[t]he vast majority of flavoring ingredients used in foods are flavorings only." 56 Fed. Reg. 28,467, 28,599 (June 21, 1991).

fect very difficult, if not impossible. The plausibility of a claim of intended effect can vary depending on, inter alia, the quantity used in the food.[60] But even so, most cases would require an examination of the specific formulation of the food product to determine the credibility of the intended effect claimed by the manufacturer.[61] For example, with HFCS, a high use level could indicate a nutritive sweetener function, and a low use level could indicate a flavor function.[62] Because of the difficulty in determining the functional use in a specific product, it would be very difficult to refute a manufacturer's claimed intended function, and thus a manufacturer could potentially claim a certain function over another for the purpose of limiting its liability in a lawsuit. However, the difficulty in determining HFCS's functional effect as an ingredient does not leave open the express preemption issue.

2. If HFCS is a Flavoring, is it an Artificial or a Natural Flavoring?

Even assuming HFCS is a "flavoring," it is still not within the reach of the NLEA express preemption statute. The possibility that HFCS could be a "flavoring" implicates the distinction between natural and artificial flavoring raised in 21 C.F.R. §§ 101.22(a)(1) and 101.22(a)(3). Recall that the express preemption provision being discussed here applies to artificial, and not natural, flavorings. In comments to the FDA, the Corn Refiners Association (CRA) claimed that the production of HFCS involved hydrolysis and enzymolysis, and that HFCS thus meets the FDA's definition of "natural flavor," since it is derived from a vegetable using the prescribed processes.[63] And at least one news story states that HFCS is produced by enzymolysis, which seems to buttress the CRA's position.[64]

If HFCS is a "natural flavoring," then the express preemption provision would not apply. Note, though, that even if HFCS *is* a "*natural* flavoring," this fact would not foreclose the suits at issue here. Consumers would still be able to argue that HFCS is not natural for purposes of the state law claims at issue, because a state law

60. Jeremiah Fasano, *supra* note 58.

61. *Id.*

62. *Id.*

63. Letter from Corn Refiners Ass'n to the Food and Drug Admin. (Nov. 14, 2006), at 15, *available at* http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-c000004-vol1.pdf.

64. Jerry DeMarco, *Snapple All Natural? Yeah Right, Judges Say*, EXAMINER.COM (June 25, 2009), http://www.examiner.com/x-2446-North-Jersey-Crime-Examiner~y2009m6d25-Snapple-all-natural-Yeah-right-judges-say.

definition of what is "natural" may differ from the technical chemical definition used by the FDA.

But exactly how strictly the FDA construes the language of 21 C.F.R. 101.22(a)(1) and (3) - particularly the phrase "derived from" - is unclear, and thus it is possible that HFCS might *not* meet the definition of a "natural flavoring," in which case it would seem to be an "artificial flavoring" by default. However, even if HFCS were considered an "artificial flavoring," the suits at issue here would still not be expressly preempted because the statute at issue, 21 U.S.C. § 343(k), is a narrow disclosure requirement of a type that would not preclude the present legal claims.

B. 21 U.S.C. § 343(k) Is A Narrow Disclosure Requirement

Even if HFCS is an artificial flavoring, and thus subject to the strictures of 21 U.S.C. § 343(k), the nature of the plaintiffs' claims are not implicated by the statute. The function of § 343(k) is to mandate a certain required disclosure on the labeling of foods that contain an artificial flavoring. Specifically, the statute states that a food is deemed to be misbranded "[i]f it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact."[65] Based on the plain reading, the statute requires that if a food contains an artificial flavoring, then the label must disclose that the food contains an artificial flavoring.[66] Thus, under the plain reading, the disclosure could be as simple as placing the words "contains artificial flavoring" on the label.

The FDA has codified regulations pertaining to the labeling of products that contain artificial flavors at 21 C.F.R. § 101.22.[67] The FDA's interpretation of 21 U.S.C. § 343(k) as revealed in its statements regarding artificial flavors can be accorded considerable weight because "a major function of § 101.22 is to distinguish between artificial and natural flavors for purposes of 21 U.S.C. § 343(k)."[68] This indicates that the FDA has carefully considered what is required by § 343(k).

The FDA's interpretation of § 343(k) is revealed by the agency's paraphrase of 21 U.S.C. § 343-1(a)(3), the express preemption provision. The FDA interprets that statute as a "requirement that the

65. 21 U.S.C. § 343(k) (2006).

66. This reading is supported by the fact that many food labels include the term "artificial flavor" in the actual ingredient list.

67. 56 Fed. Reg. 28,467, 28,615 (June 21, 1991).

68. 56 Fed. Reg. 28,467, 28,599 (June 21, 1991).

label states whether a food contains any artificial flavoring, artificial coloring, or a chemical preservative that is not identical to the requirements of section [343(k)] of the act."[69] The FDA has also stated that "[t]he act specifically requires in section [343(k)] that when a food contains any artificial flavoring, artificial coloring, or chemical preservative, the label must state that fact."[70]

A specific example of the language required to disclose the presence of something within the purview of § 343(k) can be found in the Federal Register. There, the FDA provides an example of how a sulfating agent should be disclosed:

> "If the sulfating agent is directly incorporated in the food as a preservative, under section [343(k)], the declaration of the presence of the sulfating agent must be accompanied by an appropriate statement of this fact (e.g., 'With (common or usual name of sulfating agent), a preservative'; 'Contains _____, a preservative'; or 'to retard spoilage')."[71]

From this example, it appears that the function of the ingredient is what must be disclosed. Following the above model, if one substituted HFCS for a sulfating agent, the examples of required disclosures would be as follows: " 'With high fructose corn syrup, an artificial flavoring;' 'Contains high fructose corn syrup, an artificial flavoring.' "

Thus, it appears that 21 U.S.C. § 343(k) is a very narrow disclosure requirement that specifically pertains to the disclosure of the function of the ingredient in the food. And the functions required for disclosure are those specifically limited to those listed in § 343(k); that is, "artificial flavorings," "artificial colorings," and "chemical preservatives."

The above analysis of § 343(k) reveals why claims regarding the use of "natural" on products containing HFCS are not preempted by § 343(k). Section 343(k) does not pertain to *all* label disclosures involving ingredients that could be considered artificial flavorings. It merely requires that the presence of an ingredient functioning as an artificial flavoring be disclosed as serving that function. A "natural" claim on the label of a food containing HFCS is not a claim as to the function of HFCS as an artificial flavoring in the food. In the vast majority of cases, the "natural" claim does not pertain to a flavoring function at all. But even if the claim pertains to flavoring in

69. 56 Fed. Reg. 60,045, 60,528 (Nov. 27, 1991).
70. 56 Fed. Reg. 28,467, 28,615 (June 21, 1991).
71. 53 Fed. Reg. 50,911, 51,063 (Dec. 19, 1988).

the sense of a "natural flavoring," § 343(k) is still not applicable, because § 343(k) only applies to an "artificial flavoring" functioning as such. Plaintiffs in HFCS cases are not seeking to impose any requirement regarding the labeling of "artificial flavorings," functioning as such, that differs from § 343(k).

Further, the plaintiffs in these HFCS cases are attempting to enforce state law as to what *cannot* be placed on the label of a food containing HFCS. Federal law (via § 343(k)) speaks to what *must* be disclosed, and speaks to a narrow disclosure.[72] The only way a claim as to what *cannot* be placed on a label could run afoul of § 343(k) is by requiring that an ingredient used to serve a function listed in § 343(k) cannot be labeled in accordance with § 343(k). For instance, if HFCS was used as an artificial flavoring in a food, a state could not require that the term "artificial flavoring" be absent from the label. The plaintiffs in these cases are in no way seeking such a requirement. They are merely alleging that the use of the term "natural" on products containing HFCS violates state law; and these claims, however they are argued under state law, have no bearing on 21 U.S.C. § 343(k).

C. Court Decisions On Whether HFCS Claims Are Expressly Preempted

Thus far, only one court has explicitly ruled that HFCS claims are not expressly preempted based on federal law.[73] The *Lockwood* court gave minimal attention to the argument, and perhaps focused attention on the wrong analytical component of the express preemption argument, by simply noting that the plaintiffs did not allege that defendant's product (pasta sauce) contained an artificial flavor-

72. The Third Circuit stated its support for this interpretation of 21 U.S.C. § 343(k) in *Holk*, but did not formally enforce its interpretation, because the express preemption issue was not properly before the court. In a footnote, the court stated, "[a]dditionally, § 343(k) is a disclosure requirement – i.e., it regulates only what companies must place on a label. Holk's claims go to what a company cannot put on a label for the purposes of commercial marketing, an important distinction." Holk v. Snapple Beverage Corp., 575 F.3d, 329, 336 n.3 (3d Cir. 2009). Further, a district court adopted *Holk's* understanding of the disclosure issue in finding express preemption where a plaintiff did seek to impose disclosure requirements different from the NLEA. Turek v. General Mills, Inc., No. 09 C 7038, 2010 WL 3527553, at *6 (N.D. Ill. Sept. 1, 2010).

73. I say "based on federal law," because the court in *Hitt v. Arizona Beverage Co.* held that the plaintiff's claims were not preempted, but this holding was based on the fact that the defendants did not reference any express preemption provision at all, even when making their express preemption argument. No. 08-cv809, 2009 WL 449190 (S.D. Cal. Feb. 4, 2009).

ing.[74] Analytically, the issue of whether plaintiffs explicitly alleged that defendant's pasta sauce contained an artificial flavor is irrelevant. The relevant issue is whether HFCS – which defendant's pasta sauce contained – is an artificial flavoring. If it is, then plaintiffs are impliedly alleging that defendant's pasta sauce contains an artificial flavoring. A plaintiff cannot escape preemption merely by carefully avoiding certain terms of art and obscuring the underlying issue. Nevertheless, the court arrived at the correct legal conclusion.

The issue of express preemption of HFCS claims was not properly before the *Holk* court but, as noted above, Snapple did make the argument on appeal, and the court made several observations about the argument in a footnote. The court noted that "the FDA appears to consider HFCS a sweetener and not a flavoring, and thus the allegedly troublesome statute, § 343(k), would be inapplicable."[75] The court referred to 21 C.F.R. § 184.1866 and the *Food Chemicals Codex* to support its view.[76] The *Holk* court also interpreted 21 U.S.C. § 343(k) to be a disclosure requirement, as discussed above.[77]

IV. SAVINGS CLAUSE

The savings clause contained in the NLEA[78] reveals that Congress did not intend the act to preempt the state lawsuits at issue here:

> (1) The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section [§ 343-1] of the Federal Food, Drug, and Cosmetic Act.
> (2) The amendment made by [section 343-1(a)] and the provisions of [section 343-1(b)] shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.
> (3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food Drug and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, or-

74. Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1031 (N.D. Cal. 2009).

75. Holk v. Snapple Beverage Corp., 575 F.3d 329, 336 (3d Cir. 2009).

76. *Id.* The court's interpretation of the functional effect of HFCS conflicts with the position of at least one FDA representative, and highlights the difficulty of the "function effect" analysis. *See supra*, section III.A.1.

77. *Id.*

78. 21 U.S.C. § 343-1.

> der, or other final agency action reviewable under chapter 7 of title 5, United States Code.[79]

Subsection 6(c)(1) directs that the NLEA shall not impliedly preempt state law; the preemption must be express.[80] Subsection 6(c)(2) directs that the express-preemption provision at section 343-1 does not apply to requirements regarding food safety and component warnings. Subsection 6(c)(3) states that subsections 6(c)(1) and (2) are not to be construed to affect preemption analysis of food safety and component warnings that arise under any other source of law. A closer examination of the savings clause supports these conclusions.

A. Construction of Subsection 6(c)(1)

First, we must address the exact meaning of subsection 6(c)(1). The subsection indicates that there can be no preemption based on the NLEA, except as provided by section 343-1, the express-preemption provision. This means that practically speaking, no lawsuit based on state law can be impliedly preempted on the basis of the NLEA.[81]

The way the courts discuss the clause suggests their agreement with this interpretation. In *Holk*, a Third Circuit case that considered whether the plaintiff's state-law labeling claims were impliedly preempted by the NLEA, the court stated that "courts may not find implied preemption *based* on any provision of NLEA."[82] The court also stated that if it were to find implied preemption, it would have to do so based on federal law other than the NLEA.[83] The way the court discusses the clause suggests that it takes the first, *implied-preemption-barred*, approach to subsection 6(c)(1). In *Lockwood v. Conagra Foods, Inc.* a California federal district-court case that also considered the issue, the court took a slightly stronger stance favoring the approach, noting that the clause "disavows any implied preemption."[84] Finally, in *In re Farm Raised Salmon Cases*, a California state-court case that considered an unrelated NLEA preemption

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79. 21 U.SC. § 343-1 note (2006) (Construction).

80. However, implied conflict preemption may apply even when a savings clause otherwise bars implied preemption. *See supra* Section II.

81. Note the possible exception of conflict preemption. *Supra* note 76.

82. Holk v. Snapple Beverage Corp., 575 F.3d 329, 336 (3d Cir. 2009) (emphasis added).

83. *Id.*

84. 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).

issue, the court interpreted subsection 6(c)(1) to mean that Congress made clear that the preemptive scope of section 343-1 was to sweep no further than the plain language of the statute itself."[85] These cases seem to point to a single conclusion in favor of the *implied-preemption-barred* approach.

There is, however, an even stronger argument to be made for the *implied-preemption-barred approach* based on the statutory language itself, interpreted in light of comments made on the Senate floor upon the adoption of the amendment to the NLEA that introduced the savings clause.[86] While there is no specific reference to the meaning of subsection 6(c)(1) in the legislative history, references to the meaning of subsections 6(c)(2) and (3) are analytically useful. The pertinent comments are from Senator Orrin Hatch, and can be accorded considerable interpretive weight because he was a co-sponsor of the amendment itself.[87]

The argument focuses on how the phrase "shall not be construed" is used in subsections 6(c)(1) through (3). In subsection 6(c)(1), the statutory language is "shall not be construed to *preempt*."[88] In subsection 6(c)(2), the statutory language is "shall not be construed to *apply to any requirement*."[89] And in subsection 6(c)(3), the statutory language is "shall not be construed to *affect preemption*."[90] The bulk of Senator Hatch's comments concern subsections 6(c)(2) and (3), which pertain to state-law warning requirements (as applied to content-labeling requirements). In his comments, the Senator stated that the "uniformity section" (section 343-1) "does not preempt" state-law warning requirements.[91] Later, he stated that "the provisions of [the NLEA] *may not* preempt a State warning requirement."[92] Thus, if we compare Senator Hatch's comments with the wording of the underlying text, we will see that he interpreted subsection 6(c)(2) to completely bar preemption of state warning requirements based on the NLEA. But his comments also reveal that he considers subsection 6(c)(3) to potentially *allow* preemption of state warning requirements based on sources of law outside the NLEA. Speaking of subsection 6(c)(3), he noted, "that very same [state warning] may be preempted by virtue of . . . another statutory

85. 175 P.3d 1170, 1179 (Cal. 2008).
86. 136 CONG. REC. S18056-01 (1990).
87. *Id.*
88. 21 U.S.C. § 343-1 (2006) (emphasis added).
89. *Id.* (emphasis added).
90. *Id.* (emphasis added).
91. 136 CONG. REC. S16607-02 at S16611 (1990).
92. *Id.* (emphasis added).

provision."[93] We may apply his comments to the respective underlying phrases as follows:

> "shall not be construed to apply to any requirement" = preemption barred
>
> "shall not be construed to affect preemption" = preemption not barred

If we interpret subsection 6(c)(1) in light of the meaning given to the other "shall not be construed" phrases, we are led to the conclusion that subsection 6(c)(1) is a complete bar to NLEA-based implied preemption. Subsection 6(c)(1) is much closer in form to subsection 6(c)(2), which altogether bars NLEA-based implied preemption, than it is to subsection 6(c)(3), which leaves the door open to preemption based on other sources of federal law. Subsection 6(c)(1) states that the NLEA "shall not be construed to preempt." This is very similar to the subsection 6(c)(2) language, "shall not be construed to apply." Both suggest a complete bar when compared with subsection 6(c)(3), where the phrase is "shall not be construed to affect preemption." The addition of the word "affect" leads to a more restrained approach than that found in subsections 6(c)(1) and (2). That these phrases are repeated in such close proximity, in such a short provision, and yet differ slightly as to wording, suggests that Congress intended for subsections 6(c)(1) and (2) to have a different meaning than subsection 6(c)(3).

B. Construction of Subsections 6(c)(2)-(3)

Under this construction of subsection 6(c)(1), the NLEA may not be used to support an implied preemption defense. Some defendants have therefore preferred to argue that their preemption defenses derive from portions of the FDCA that were not amended by the NLEA, and thus fall outside the scope of the protections afforded by the savings clause.[94] These defendants appeal to subsection 6(c)(3) of the savings clause, which states:

> The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food Drug and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, or-

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93. *Id.*

94. For example, in *Lockwood*, the defendant based its preemption argument on FDA "misbranding" regulations. Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).

> der, or other final agency action reviewable under chapter 7 of title 5, United States Code.[95]

They argue on the basis of subsection 6(c)(3) that the limited nature of preemption in the NLEA and savings clause may not be used to infer a lack of congressional intent to preempt when the defendants' preemption arguments arise under other parts of federal law. In such cases, the argument goes, the NLEA and subsections 6(c)(1) and (2) may not be used to affect the preemption analysis pertaining to other federal law.

Thus, the effect of the savings clause on implied preemption defenses based on portions of federal law other than the NLEA is also important, and is informed by subsections 6(c)(2) and (3). Subsection 6(c)(2) states that 21 U.S.C. §§ 343-1(a) and (b) (the express preemption provisions) do not apply to food-safety and component-warning requirements. Subsection 6(c)(3) states that subsections 6(c)(1) and (2) are not to be construed to affect preemption analysis "of any such requirement" that arises under any other source of law. Taken together, subsections 6(c)(1) and (2) do not support the defendants' argument.

A plain reading suggests two possible effects of the savings clause on implied-preemption arguments based on portions of federal law outside the NLEA. One, the NLEA is barred from having any effect on preemption analysis at all. This is the broader reading. Or two, the clause is only barred from having an effect on preemption analysis pertaining to state-law food-safety and component-warning requirements. This is the narrower reading. How one interprets subsection 6(c)(3) will dictate which possibility is correct.

Defendants prefer the broader reading because under it, if a defendant grounds its preemption argument in portions of the FDCA outside the NLEA, the court cannot use the NLEA or the savings clause to infer a lack of intent to preempt in the food-and-beverage-labeling field. For example, in *Lockwood v. Conagra Foods, Inc.*, the court reasoned that "the existence of a savings clause which explicitly disavows any implied preemption with certain subject areas [i.e. those covered by the NLEA] suggests that Congress did not intend to occupy the field of other related subject areas."[96] This kind of reasoning would be prohibited under possibility one, because under it, the savings clause in the NLEA cannot be construed to af-

95. 21 U.S.C. § 343-1 note (2006).
96. 575 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).

fect preemption outside the NLEA in any way. However, Congress seems to have intended the narrower reading.

The decisive interpretive issue is the meaning of the phrase "any such requirement" in subsection 6(c)(3). If the phrase refers to the state-law warning requirements mentioned in subsection 6(c)(2), then the narrow reading is correct. If the phrase has a more general meaning, and refers to any state-law requirement that concerns any of the specified provisions of federal law, then the broader reading is correct. Senator Hatch's comments on the amendment make it clear that the phrase refers to the state law warning requirements in subsection 6(c)(2). Speaking of subsection 6(c)(3), the Senator said:

> Specifically, the uniformity amendment has two components. First, it states that the carefully crafted uniformity section of this legislation is limited in scope. That section does not preempt or affect a requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of a food or a component of a food. An example of such a warning would be a statement required under a state law regarding the possibility of an allergic reaction from a component of a food. Perhaps more important is the second rule of construction embodied in [subsection 6(c)(3)], which makes it abundantly clear that the lack of preemption of such warning requirements in the legislation is not extrapolated, through overzealous statutory interpretation, to imply that preemption of such warning requirements is somehow affected by the enactment of limited preemption in this legislation. Specifically, the amendment provides that the bill" does not affect preemption, express or implied, of *any State or local warning requirement* which arises under the Constitution, any other provision of the Federal Food, Drug, and Cosmetic Act, any other Federal law, or any regulation, order or other final agency action reviewable under the Administrative Procedure Act.[97]

In Senator Hatch's own paraphrase of subsection 6(c)(3), he substitutes the phrase "any State or local warning requirement" for the phrase "any such requirement," found in the actual amendment. This substitution indicates that the phrases are equivalent. It should be noted that Senator Hatch made a statement immediately following the one above that leaves open the possibility of his preference for the broader approach. He said, "[t]he decision of Congress in this legislation to specifically preempt certain State or local requirements is not evidence, one way or the other, of any Congressional view about the existence of preemption which may arise from other existing legal authorities or actions."[98]

But the above statement occurred in the immediate context of his comments on state-law warning requirements, which suggests

97. 136 CONG. REC. S16607-02 at S16611 (1990) (emphasis added).
98. *Id.*

that he had those requirements in mind when he made the statement. And because he said nothing about the type of requirements outside the NLEA that may sustain a preemption defense, we may be reasonably confident that he is still speaking within the "state warning requirements" frame of reference.

Further, this narrower reading is supported by *Lockwood*. There, the court noted that a fair reading of the phrase "any such requirement" in subsection 6(c)(3) is one that interprets the phrase as referring to the topic of food-safety or component warnings in subsection 6(c)(2).[99] The court did not refer to any legislative history in making this observation, so we may assume this to be its plain reading of the clause.

Taken together, these indications from the statute itself and from the case law and legislative history show that the there is no implied preemption based on the NLEA, but that the NLEA may be used to infer a lack of preemption when defendants raise preemption defenses that arise out of other sources of federal law.

V. IMPLIED FIELD PREEMPTION

A. What is the Field?

Because the claims involving HFCS in products labeled "natural" are fundamentally about labeling, any implied field preemption arguments must derive from the field of food and beverage labeling. Some defendants have preferred to argue that their preemption defenses derive from portions of the FDCA that were not amended by the NLEA.[100] However, even these portions involve food and beverage labeling.

B. Preemption Defenses Under the NLEA

As noted above, defendants in HFCS litigation have preferred to ground their preemption arguments in portions of the FDCA not amended by the NLEA.[101] The reason should be obvious based on

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99. Lockwood v. Conagra Foods, Inc., 575 F. Supp. 2d 1028, 1033 (N.D. Cal. 2009).

100. *See supra*, note 94.

101. Defendants' primary way of arguing that plaintiffs' claims fall outside the scope of the NLEA is to argue that the claims are basically misbranding claims under the FDCA. Holk v. Snapple Beverage Corp., 575 F.3d 329, 337 (3d Cir. 2009); Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).

the analysis of the savings clause above: the NLEA savings clause, § 6(c)(1), bars implied preemption based on claims arising under the NLEA. However, claims involving the use of "natural" on products containing HFCS do fall within the NLEA, and therefore are not preempted unless expressly preempted by 21 U.S.C. § 343-1, or through conflict preemption.

The FDA policy on the use of the term "natural" is a central part of the analysis of claims involving the term's use on products containing HFCS. This being the case, the law under which the FDA has undertaken the development of its position on the use of the term "natural" should be given great weight in determining whether the claims alleged fall under the NLEA or portions of the FDCA outside the NLEA.

The *Lockwood* court recognized this argument, and its import, and came to the following conclusion:

> [W]hen the FDA considered whether to adopt formal regulations defining the use of the term 'natural' on food labels it did so pursuant to the NLEA amendments to the FDCA - not the FDCA provisions left untouched by the NLEA. *See* 58 F.R. 2302-1 (1993) ("This action is part of the food labeling initiative of the Secretary of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments)."). In other words, if the FDA were to adopt formal regulations defining the use of 'natural' on a food label, it would do so pursuant to the NLEA - the very act that unambiguously provides that there is no preemption of state laws except as expressly provided.[102]

Thus, there is a strong argument that the claims involving the use of the term "natural" do arise under the NLEA, because the FDA's policy on the term has been developed under the NLEA. If this argument is correct, then the claims are not subject to implied field preemption, and cannot be, because of the savings clause.

C. Preemption Defenses Under the FDCA Generally

Though there is a strong case to be made that claims involving the use of the term "natural" on labels fall within the NLEA and therefore cannot be impliedly preempted, even if the claims fall outside the NLEA, they are still not impliedly preempted based on FDA regulation in the food-and-beverage labeling field. As noted above, because regulation of health and safety issues generally, and food and beverage labeling in particular, have traditionally been areas of

102. Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1033 (N.D. Cal. 2009).

state regulation, Congressional intent to supersede state law in the field must be "clear and manifest."[103] Contrary to being clearly and manifestly intended to supersede state law in the food-and-beverage labeling field, Congressional activity and FDA regulation strongly appear to envision and permit simultaneous state law in the field.

1. Inference Drawn from Express Preemption Provision

The first and primary indicator of Congressional intent to allow for state regulation in the food-and-beverage labeling field is the NLEA express savings clause. The NLEA is part of the FDCA's food and beverage labeling provisions. Therefore, we may infer Congressional intent as to the field by looking at the NLEA itself.[104]

The Supreme Court has noted that "an express definition of the pre-emptive reach of a statute 'implies' - i.e., supports a reasonable inference - that Congress did not intend to pre-empt other matters."[105] The express preemption clause at 21 U.S.C. § 343-1 is just such an express definition of preemptive reach. And while the Court has also noted that an express definition of preemptive reach "does not mean that the express clause entirely forecloses any possibility of implied pre-emption," the inference, combined with other sources of Congressional intent, suggests that Congress did not intend to preempt state-law claims of the type at issue here.[106]

The reasoning behind the non-preemption inference drawn from express preemption clauses was summarized by the *Holk* court in a paraphrase of the plaintiff's argument: "[the plaintiff] reasons that the limited nature of the express preemption provision in NLEA, which applies only to those federal laws specifically enumerated, 'would serve no purpose and would simply be surplus if Congress had intended to occupy the entire field of food and beverage labeling.' "[107] The idea, which the plaintiff argued correctly, is that if the field of food and beverage labeling were already dominated by a pervasive scheme of federal regulation that left no room for state

103. English v. General Electric Co., 496 U.S. 72, 79 (1990); Holk v. Snapple Beverage Corp., 575 F.3d 329, 334 (3d Cir. 2009).

104. Recall that, as shown above, the express savings clause in the NLEA forecloses consideration of the NLEA only as to preemption of warning requirements that arise under other sources of law. Because warning requirements are not the subject of the current analysis, the NLEA may be considered in analyzing the preemption of the labeling claims at issue here.

105. Freightliner Corp. v. Myrick, 514 U.S. 280, 288 (1995).

106. *Id.*

107. Holk v. Snapple Beverage Corp., 575 F.3d. 329, 337 (3d Cir. 2009).

regulation, a limited express-preemption provision would be unnecessary, because *every* state law requirement in the field would already be preempted.

The California Supreme Court, in *In re Farm Raised Salmon Cases*, advanced another persuasive argument for inferring the lack of implied preemption based on the express preemption statute. The court said:

> Various provisions of the FDCA clearly demonstrate that "Congress knows how to write a preemption clause" when it wants to (*Consumer Justice, supra*, 99 Cal.App.4th at p. 1059, 121 Cal.Rptr.2d 749) and that "the [FDCA] evidences, far from implied preemption, an instance of implied *non* preemption." (*Id.* at p. 1063, 121 Cal.Rptr.2d 749.) Congress enacted numerous specific express preemption provisions in the FDCA. (See, e.g., §§ 360k (medical devices), 360ss (radiation emissions), 379r (nonprescription drugs), 379s (cosmetics).) The inference to be drawn from these provisions is that Congress, in light of the history of dual state-federal cooperation in this area, did not intend to limit states' options in a broad fashion. Indeed, the preemption provision at issue here, section 343-1, demonstrates Congress's care in deciding what to preempt and what to allow. Section 343-1 is notable both for the number of misbranding provisions it deals with (approximately 20) and for the detailed nature of its preemptive scope. The language of section 343-1 and the NLEA's express preemption provision is further evidence that Congress chose carefully the manner with which it preempted certain state labeling laws.[108]

2. Other Expressions of Congressional Intent

There is also ample evidence that Congress was well aware of the existence of the regulatory roles played by the states prior to the enactment of the NLEA, and that Congress intended to preserve those roles while enacting the NLEA. The sponsor of Amendment 3125 (discussed above), Senator George Mitchell, commented on the balancing of state and federal roles sought in the NLEA. The Senator noted that "[i]t is also important that [the NLEA], which requires nationally uniform nutritional labeling, is sensitive to the regulatory roles played by the States. This bill has been refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory authority where it is appropriate."[109] This statement suggests exactly the type of tension the Supreme Court was concerned about when it said "[t]he case for federal preemption is particularly weak where Congress has indicated its

108. *In re* Farm Raised Salmon Cases, 175 P.3d 1170 (Cal. 2008).
109. 136 CONG. REC. S16607-02, 16609 (1990).

awareness of the operation of state law in fields of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them."[110]

VI. CONFLICT PREEMPTION

Claims regarding the use of HFCS in products labeled "natural" are not preempted by implied conflict preemption. They are not preempted due to the impossibility of compliance with state and federal requirements, and they are not preempted by raising an obstacle to the accomplishment of the purposes of Congress.

A. Impossibility

The claims in question are not preempted due to the impossibility of dual compliance because, as the Lockwood court noted, "[a] manufacturer could comply, that is, not violate the FDA's policy as to use of the term 'natural' and still comply with state law as articulated by plaintiffs in this case."[111] The claims being brought basically allege that, under state law, products containing HFCS should not be labeled "natural," because HFCS is not natural. Manufacturer defendants can physically comply with the requirements of state law, as alleged, and FDA policy. Because the state law requirements alleged by the plaintiffs in HFCS cases are arguably more restrictive than the FDA's policy on "natural," defendants' compliance with the state law requirements would pose no conflict to their compliance with the less restrictive FDA policy. Further, in the *Holk* appellate case, Snapple did not even raise impossibility of dual compliance as a conflict preemption defense.[112]

B. Obstacle

Nor are the claims in question preempted because the state law requirements they seek to enforce stand as an obstacle to the accomplishment of the objectives of Congress. The purpose and ob-

110. Wyeth v. Levine, 129 S.Ct. 1187, 1200 (2009) (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc. 489 U.S. 141, 166-167 (1989). However, food and beverage labeling is not necessarily a "field of federal interest," given the historic food safety regulatory roles played by the states.

111. Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1034 (N.D. Cal 2009).

112. Brief for Defendant/Appellee Snapple Beverage Corp., Holk v. Snapple Beverage Corp., 575 F.3d 329 (3d Cir. 2009) (No. 08-3060), 2009 WL 383336.

jectives of Congress regarding the use of "natural" may be discerned though the FDA's regulation of the use of the term, because of the authority delegated to the FDA by Congress. Thus, to determine whether any state law requirements alleged by the plaintiffs pose an obstacle to Congressional purpose, one must determine whether the FDA's regulation of the use of "natural" evidences any particular purpose that is entitled to preemptive effect. This purpose, if it exists, must be manifested in law. As one court noted, "it is federal *law* which preempts contrary state law; nothing short of federal law can have that effect."[113] The reasoning behind this idea is that if there is no federal purpose, there is nothing with which state law can conflict, and thus no conflict preemption. To this end, the FDA has noted that "[i]f there is no applicable Federal requirement that has been given preemptive effect by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under [the NLEA] for Federal preemption."[114]

Various courts have rightly determined that the FDA has not evidenced such a preemptive purpose through law. The *Holk* court put it thus: "[T]here is no conflict preemption in this case because there is no FDA policy with which state law could conflict."[115]

In determining whether a federal pronouncement is entitled to preemptive effect, courts focus on the process by which the decision is arrived at. For example, in a Third Circuit case, the court declined to "afford preemptive effect to less formal measures lacking the 'fairness and deliberation' which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law."[116] That court also said that "[c]ourts with good reason are wary of affording preemptive force to actions taken under more informal circumstances."[117] This reflects a desire to limit preemption to those instances in which Article VI of the Constitution truly applies; that is, where it is really the "supreme law of the land" that is doing the preempting. But it also reflects a policy desire. Thus, the Third Circuit noted:

> Regularity of procedure - whether it be the rulemaking and adjudicatory procedures of the APA or others which Congress may provide for a par-

113. Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 243 (3d Cir. 2008) (emphasis original).

114. 56 Fed. Reg. 60,528, 60,530 (Nov. 27, 1991).

115. Holk v. Snapple Beverage Corp., 575 F.3d 329, 342 (3d Cir. 2009).

116. Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 245 (3d Cir. 2008) (emphasis original).

117. *Id.*

> ticular purpose - not only ensures that state law will be preempted only by federal 'law,' as the Supremacy Clause provides, but also imposes a degree of accountability on decisions which will have the profound effect of displacing state laws, and affords some protection to the states that will have their laws displaced and to citizens who may hold rights or expectations under those laws.[118]

The FDA has not issued any policy statements on the use of "natural" that meet the standards outlined above. The FDA does not have a formal policy on the use of the term "natural." When the FDA referenced its policy in a Federal Register statement in 1991, the FDA referred to the policy as "informal."[119] In the same Register statement, the FDA said that the use of the term on labels was "of considerable interest to consumers and industry," and noted that it was considering establishing a definition for the term.[120] In fact, the FDA stated that if an adequate definition of the term were established, "the ambiguity surrounding use of the term that results in misleading claims could be abated."[121] This shows that the FDA was aware of the precise problem raised by the litigants in HFCS cases today. And yet, even though the FDA recognized this problem, it "decided not to define the term."[122] Further, the FDA recently denied a specific request by several federal district court judges to determine whether HFCS qualifies as "natural."[123] Recognizing the problem resulting from the lack of a definition of "natural" and consciously abstaining from a rulemaking regarding the term suggests that the FDA, and therefore Congress, does not have the "purpose" to regulate the term's use.[124]

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118. *Id.*

119. 56 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991).

120. *Id.*

121. *Id.*

122. 58 Fed. Reg. 2302, 2397 (Jan. 6, 1993).

123. *See, e.g.*, Coyle v. Hornell Brewing Co., No. 08-2797 (D.N.J. Sept. 23, 2010) (order dissolving temporary stay) (the letter from the FDA denying the judge's request is attached to the order).

124. Nor does the absence of regulation evince a Congressional purpose. The Supreme Court, in *Sprietsma v. Mercury Marine*, noted that mere absence of regulation cannot be given preemptive weight as an agency's determination not to regulate, without an "'authoritative' message" that the absence is intended as such. The Court said "although the Coast Guard's decision not to require propeller guards was undoubtedly intentional and carefully considered, it does not convey an "authoritative" message of a federal policy against propeller guards." Sprietsma v. Mercury Marine, 537 U.S. 51, 67 (2002). This is parallel to the FDA's actions here. The FDA's decision not to define "natural" was carefully considered, but it does not convey an authoritative message of a federal policy against any definition of the term, as evidenced by the very existence of an informal policy. *Id.*

Nor does the informal policy on "natural" sustain preemptive authority based on a fair process analysis. The *Holk* court rightly pointed out that the fact that the FDA requested comments on the term's use "in reaching a decision on any future FDA course of action" implies that the agency's informal policy pre-dated a request for notice and comment.[125] And, noted the *Holk* court, "[b]ecause a search of the Federal Register results in neither earlier references to this policy nor other requests for comments on the use of the term 'natural,' the record demonstrates that the FDA arrived at its policy without the benefit of public input."[126] This suggests that the FDA's current informal policy was arrived at in a way that falls far short of the requisite "fairness and deliberation" that courts have looked for in other preemption contexts.

Further, the FDA did not respond to all of the comments it received. The agency noted one comment that it considered "moot" in light of its decision not to define the term.[127] And even after discussing several comments, the agency said that "there are many facets of this issue that the agency *will* have to consider if it undertakes a rulemaking to define the term."[128] This illustrates an incomplete consideration of all the facets of the issue, and an admission that the agency will have additional issues to consider before making a final rule. Again, as *Holk* recognized, all of these facts indicate a lack of the "fairness and deliberation" required for the FDA policy to have preemptive effect.

Finally, an agency letter authored by the FDA proclaiming HFCS to be "natural" is not entitled to preemptive effect. In April 2008, FoodNavigator-USA.com published an article that quoted an FDA representative as saying HFCS would not comply with the agency's policy on "natural."[129] Then on July 3, 2008, the same FDA representative said, in a letter to the Corn Refiners Association, that the FDA *would* consider HFCS to meet the agency's policy on "natu-

125. Holk v. Snapple Beverage Corp., 575 F.3d 329, 341; 56 Fed. Reg. 60,045, 60,467 (Nov. 27, 1991).

126. *Id.*

127. 58 Fed. Reg. 2125, 2397 (Jan. 22 1991).

128. 58 Fed. Reg. 467, 2407 (Jan. 6, 1993) (emphasis added).

129. Laura Crowley, *HFCS is Natural, Says FDA in a Letter*, FOOD NAVIGATOR-USA (July 8, 2008), http://www.foodnavigator-usa.com/Financial-Industry/HFCS-is-natural-says-FDA-in-a-letter.

ral," depending on how the HFCS is made.[130] However, this letter cannot be accorded preemptive weight.[131]

The court in *Fellner* stated, "we have found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption."[132] The letter does not even appear to constitute an advisory opinion, which itself may not operate as a legal requirement.[133]

VII. CONCLUSION

Regardless of the legal merits of state-law claims that HFCS is not "natural," the claims themselves are not preempted by federal law. Even without applying the presumption against preemption, the claims are neither expressly nor impliedly preempted. Applying the presumption, the lack of preemption is even clearer. However, there are serious problems with the current regulatory structure that should be addressed.

If the FDA is going to claim control over food-and-beverage labeling standards, the agency should create a more objective method for determining the functional effect for which ingredients are added to foods and beverages. The opacity of this determination regarding HFCS is not unique to that particular ingredient. The vast implications for litigation portended by 21 U.S.C. § 343(k), and thus the importance of distinctions regarding the functional effects of ingredients, are enough reason to undergo a rulemaking to develop a more objective and predictable method of distinction. Consumers should not be forced to hire a food chemist or commence litigation in order to determine the functional effect of an ingredient.

However, the FDA has illustrated its inability to serve the interest of consumers *and* manufacturers on the "functional effect" issue, and labeling issues more broadly. A better approach would be to leave all labeling requirements up to the states via consumer fraud litigation. That way, consumers would be their own judges regard-

130. Letter from the Food and Drug Admin. to Corn Refiners Ass'n (July 3, 2008), *available at* http://www.corn.org/wp-content/uploads/2008/07/FDAdecision7-7-08.pdf (emphasis added).

131. Apart from any other legal consideration, the fact that the agency's view is so vacillating weighs against according either of these letters authoritative weight.

132. Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 245 (3d Cir. 2008).

133. 21 C.F.R. § 10.85(j) (2010).

ing what their interests in labeling are, and how to protect them, through the courts and the jury system. This would result in a more efficient use of economic and bureaucratic resources, and more accurately reflect the issues that consumers are concerned with, rather than forcing consumers and industry to expend exorbitant sums merely to address the regulatory hurdles that encumber litigation in the current system, on top of the costs of litigating the underlying issues. Federal encroachment on the states' police powers in the labeling field has left confusion and stagnation in its wake. The federal leviathan has certainly bitten off more than it can chew. But, unfortunately, when it comes to the issue of "natural" labeling claims, it is the consumer who is choking.

Public interest in "natural" claims and HFCS shows no sign of abating anytime soon. The current regulatory structure, while not preemptive as to the state-law claims examined in this comment, should be clarified, if not abolished. The right changes will restore consumer confidence in food and beverage labeling by creating greater clarity and simplifying civil legal enforcement.